

R E M A R K S

Favorable reconsideration is respectfully requested in view of the preceding amendment and following comments. By this Amendment new independent Claim 21 has been added. Claims 1 to 21 are pending in the application.

Filed separately herewith is a Credit Card Payment Form PTO-2038 in the amount of \$998.00 which includes \$980.00 for a three-month Petition for Extension of Time (also filed separately herewith) and \$18.00 for one additional dependent claim over 20. If the amount is in error, the Patent and Trademark Office is authorized to debit or credit, as appropriate, Deposit Account No. 06-1358.

Newly presented claim 21 further limits the agonist of claim 3 to the sole essential active ingredient for inhibiting hair growth and thus clearly distinguishes over the subject matter claimed in copending Application No. 10/345,399.

Antecedent support for this claim is provided, e.g., by original claims 1 and 3.

The rejection of claims 1 to 20 "under 35 U.S.C. 112, first paragraph" is respectfully traversed in the same manner and for the same reasons as set forth in Applicants' Remarks of November 20, 2003, which are repeated by reference. Issue is respectfully taken with the unsupported and unsupportable position:

Applicants' specification and prior art do not enable the claimed method of attenuating or reducing the growth of hair by using the recited composition. The specification and prior art do not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim without undue experimentation.

The determination of what constitutes undue experimentation in the given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the

state of the art. This test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine. *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988).

The nature of experimentation required, if any, is purely and completely routine - merely determining whether or not any particular prostaglandin EP-3 receptor agonist is or is not hair growth inhibiting. Nothing could be more routine than that. Clearly, no undue experimentation is needed. The level of one of ordinary skill in this art is high, examples are provided in the specification, and the quantity of experimentation needed is minimal.

Issue is further taken with the allegation: "if any experimentation is necessary, it is undue." The authority of such a proposition is requested, and absence of providing such authority must be regarded as an admission that no such authority exists.

Reference is made to Katsu abstract (CAPLUS Acc. No. 1987:55617). Citation of an abstract without citation and reliance on the underlying scientific document itself is generally inappropriate with both the abstract and underlying document being prior art. Abstracts often are not written by the author of the underlying document and may be erroneous. A proper examination under 37 CFR §1.104 should be based on the underlying documents and translations, where needed. Accordingly, the preferred practice is for the Examiner to cite and rely on the underlying document. In the event a reference is in a foreign language, if the applicant does not wish to expend resources to obtain a translation, the applicant may wish to request the Examiner to supply a translation. If a translation is not supplied by the Examiner, the applicant may wish to consider seeking supervisory relief by way of a petition (37 CFR §1.181) to have the Examiner directed to obtain and supply a translation.

Ex parte Jones, 62 U.S.P.Q.2d 1206, 1208, 1209 (BPAI 2001).

In the event that Katsu is relied upon for any purpose whatsoever, the Examiner is respectfully requested to cite and rely upon the underlying document.

The abstract of Katsu relates to a hair tonic and does not mention any hair growth associated with PGE1. This document does not contradict the fact that a lotion containing PGE1 prostaglandin (prostaglandin EP3 receptor agonists) would be able to reduce hair growth, as demonstrated by Example IV of the specification of the subject application.

The rejection of claims 1 to 20 "under 35 U.S.C. 112, second paragraph" is also respectfully traversed. Applicants have set forth and exemplified a genius and have also provided further direction, e.g., in the text found in the paragraph bridging pages 3 and 4 and in the final paragraph on page 4 of the specification. One of at least ordinary skill in the subject art would need no further assistance in understanding the involved subject matter.

The rejection of claims 1 to 20 "under the judicially created doctrine of obviousness-type double patenting" is also respectfully traversed. All of the claims of the subject application require a hair growth inhibiting prostaglandin EP-3 receptor agonist, which is not called for by any of the claims of copending Application No. 10/345,399. The several sets of claims are thus distinguishable, one from the other. Reconsideration and withdrawal of the obviousness-type double patenting rejection is thus in order and are respectfully solicited. The copending application is directed to the action of prostaglandins EP2 and EP4 receptor antagonists which are clearly different from structures of EP3 receptor agonists, evidence of the clear distinction between basic subject matter of the respective applications is provided by Narumiya (*Physiological Reviews*, Vol. 79, No. 4, 1999, pp 1193-1226) disclosing the different structures of prostanoid receptors and properties of these receptors. Narumiya (p. 1198) explains that: "there is only this limited extent of homology even

Serial No.: 09/917,274
Atty. Docket No.: P66901US0

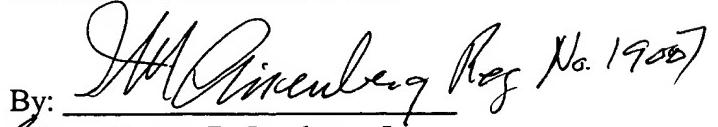
among the four subtypes of PGE receptors, which makes it difficult to get any insight into the areas determining the ligand binding specificity of each receptor, simply by comparing the sequence of one receptor with those of the receptors for other prostanoids." Concerning the molecular evolution of the prostanoid receptors, the author notes (p. 1201): "The relaxant receptors, which mediate increases in cAMP and induce smooth muscle relaxation, consists of the IP, DP, EP₂, and EP₄ receptor. . . . The EP₃ receptor is an inhibitory receptor that mediates decreases in cAMP and inhibits smooth muscle relaxation. . . . The prostanoid receptor cluster was further divided into three subclusters: cluster 1 consists of the relaxant receptors, EP₂, EP₄, . . . ; and cluster 3 consists of the inhibitory receptor EP₃." (p. 1202).

These different citations illustrate the structural and functional differences between EP2, EP3 and EP4 receptors. Indeed, agonists or antagonists directed against these receptors are also different.

Having overcome all outstanding grounds of rejection, favorable action on the merits is in order and is respectfully solicited.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: 
Harvey B. Jacobson, Jr.
Reg. No. 20,851

400 Seventh Street, N. W.
Washington, D.C. 20004
Telephone: (202) 638-6666
Date: November 4, 2004

HBJ:IMA:cwp

R:\AISEN\11-04\P66901US0.AMD